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Virtual Law Partners LLP				
555 Bryant Street				
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Palo Alto, CA 94301				
EXAMINER				
BUL PHUONG T				
ART UNIT		PAPER NUMBER		
1638				
NOTIFICATION DATE		DELIVERY MODE		
12/10/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@virtuallawpartners.com

Office Action Summary

Application No.

10/580,868

Applicant(s)

SPANGENBERG ET AL.

Examiner

Phuong T. Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-48 is/are pending in the application.
- 4a) Of the above claim(s) 30, 32, 34, 36, 38-42 and 44-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29, 31, 33, 35, 37 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- Paper No(s)/Mail Date 5/31/07, 4/20/09
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The Office acknowledges the receipt of Applicant's restriction election filed September 21, 2010. Applicant elects Invention I, IRIP from *Deschampsia* species and SEQ ID NO:7 without traverse. Claims 29-48 are pending. Claims 29(ii), 29(iv), 29(vii), 30, 32, 34, 36, 38-42 and 44-48 and all nonelected SEQ ID NOs. have been withdrawn from examination. Claims 29(i, iii, v, vi, viii), 31, 33, 35, 37 and 43 to the extent of SEQ ID NO:7 are examined in the instant application. This restriction is made FINAL.

Because SEQ ID NO:7 was first disclosed in PCT/AU04/01633, Applicant's earliest priority benefit is November 24, 2004.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on May 31, 2007 and April 20, 2009 have been considered. Signed copies are attached.

Claim Objections

3. Claim 29 is objected to because claim 29 recites nonelected sequences and nonelected inventions. Correction is required.

Drawings

4. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings submitted are illegible. Moreover, each page must have a separate Figure designation. For example, "Fig. 2A (cont.)" is not a valid figure designation. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office

action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See p. 28, for example.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 29, 31, 33, 35, 37 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In claim 29(iii), "a" should be amended to "the". Otherwise, the claim reads on a 2-base sequence, which does not appear to be Applicant's intention.

In claim 29(v), "functionally active fragment or variant" is unclear because no function is recited. A single amino acid is functionally active. It is unclear whether "variant" refers to both naturally occurring and synthetic variants, and what functional activity the variant possesses. The specification gives examples but does not provide a definition.

Claim 29 (vi) reads on a 2-base sequence, which does not appear to be Applicant's intention. It is suggested "fully" be inserted before "complementary".

In claim 29(viii), it is unclear how the claimed RNA sequence "corresponds" to the above sequences. Does "correspond" mean the RNA version of a DNA sequence, or is the RNA complementary to the DNA sequence?

In claim 31, it is suggested "A" be amended to "The" for proper antecedence. See also claims 35, 37 and 43.

In claim 37, it is unclear what is retained in the "derived" product. It is suggested "derived" be amended to "obtained".

In claim 43, it is unclear how the preparation differs from the nucleic acid of claim 29. Does Applicant intend to claim a vector?

Clarification and/or correction are required.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claim 37 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Due to gene segregation in sexual hybridization, a progeny plant, seed or other plant part of a transgenic plant cell or plant may not contain transgenic material, and thus the claim reads on a product of nature.

Claim Rejections - 35 USC § 112, first paragraph

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 29, 31, 33, 35, 37 and 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:7, does not reasonably provide enablement for "a functionally active fragment or variant". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification discloses SEQ ID NO:7 encodes an ice recrystallization inhibition protein (IRIP) from *Deschampsia antarctica*. The specification does not disclose a functionally active fragment or variant of IRIP or SEQ ID NO:7. No function is set forth in the claims. A "functionally active fragment" does not necessarily have the same function as an IRIP, as a single amino acid is functionally active. Applicant provides no guidance as to which portion of an undisclosed IRIP sequence or SEQ ID NO:7 is essential for its functional activity, or what mutations are encompassed by its variant. Such mutations include base additions, deletions, substitutions and any combination thereof anywhere within IRIP or SEQ ID NO:7. In fact, the variant does not have to have any sequence identity to SEQ ID NO:7. It is unpredictable which bases or regions can be deleted or mutated without abrogating its activity, however such activity is defined. The state of the art does not teach which region of an IRIP or the protein encoded by SEQ ID NO:7 is the functional domain of an IRIP. While one skilled in the art can readily make deletions and/or mutations, further guidance is necessary as to how inoperable embodiments can be readily eliminated without resorting to random trial and error. Given the lack of guidance, working examples, unpredictability and state of

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the art, one skilled in the art would not be able to make and use the claimed invention as commensurate in scope with the claims without undue experimentation.

12. Claims 29, 31, 33, 35, 37 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant does not disclose a representative number of species within the generic recitation of "IRIP from a *Deschampsia* species", a functionally active fragment or variant as set forth in the claims. SEQ ID NO:7 was obtained from *Deschampsia antarctica*. The claims encompass sequences having no sequence identity to SEQ ID NO:7. One skilled in the art would not be able to reliably predict the structures of other IRIPs based upon the disclosure of SEQ ID NO:7. The claims encompass other sequences not known or disclosed in the art. Applicant does not disclose what other *Deschampsia* species possess IRIPs, and what their structures are. It is unpredictable whether each *Deschampsia* species only possess one IRIP, or whether there are other IRIPs that have no significant sequence identity to SEQ ID NO:7. The consensus sequences or motifs alone are insufficient to determine the structures of the full-length proteins. The claims encompass mutants and allelic variants and thus imply that structural variants exist in nature, yet no structural variant has been disclosed. The implication is there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known. There are insufficient relevant identifying

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characteristics to allow one skilled in the art to predictably determine such mutants, allelic variants and IRIPs from other plants and organisms. While one skilled in the art can readily generate a genus of sequences having various sequence identities to SEQ ID NO:7, it is unpredictable which species within the genus would have the same functional activity as SEQ ID NO:7. Similarly, with regard to functionally active fragments, while one skilled in the art can generate IRIP fragments and fragments of SEQ ID NO:7 of various sizes, it is unpredictable which fragments would have the same functional activity as SEQ ID NO:7 or a *Deschampsia* IRIP. Accordingly, there is lack of adequate description to inform a skilled artisan that Applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/ Vol.66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

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Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

14. Claims 29, 31, 33, 35, 37 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Demmer et al. (USPN 7132263 (A)). Demmer teaches various nucleic acid sequences encoding antifreeze proteins from *Lolium perenne* which either contain functionally active fragments or are variants of IRIP from a *Deschampsia* species and SEQ ID NO:7 (SEQ ID NO: 8 encoding SEQ ID NO:20 and SEQ ID NO:10 encoding SEQ ID NO:22). Demmer also teaches RNA, nucleic acid construct, vector, transgenic plant cell and plant. Accordingly, Demmer anticipates the claimed invention.

15. Claims 29, 31, 33, 35, 37 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Jarman et al. (USPN 6852841 (B)). Jarman teaches a nucleic acid sequence encoding an antifreeze polypeptide (SEQ ID NOs. 1 and 2) from *Lolium perenne* which either contain functionally active fragments or are variants of IRIP from a *Deschampsia* species and SEQ ID NO:7. Jarman also teaches nucleic acid construct, vector, transgenic plant cell and plant. Accordingly, Jarman anticipates the claimed invention.

Remarks

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong T. Bu/
Primary Examiner, Art Unit 1638